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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/973,375	10/09/2001	Donald Gerald Stein	07157/239838 (5543-17)	5877

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EXAMINER
JIANG, SHAOJIA A

ART UNIT	PAPER NUMBER
1617	12

DATE MAILED: 04/14/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/973,375	STEIN ET AL.	
	Examiner	Art Unit	
	Shaojia A. Jiang	1617	

--The MAILING DATE f this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 28 March 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires *4* months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☒ A Notice of Appeal was filed on *28 March 2003*. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attachment*.

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: *none*.

Claim(s) objected to: *none*.

Claim(s) rejected: *1-20 (all)*.

Claim(s) withdrawn from consideration: *none*.

8.☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____

10.☐ Other: _____

SREENI PADMANABHAN
PRIMARY EXAMINER 4/11/03

Advisory Action

This Office Action is a response to Applicant's response after FINAL filed on March 28, 2003.

5. Applicant's remarks filed March 28, 2003 with respect to the rejection of claims 1-20 made under 35 U.S.C. 103(a) as being unpatentable over Roof et al. (of record) and Gee et al. (Re. 35,517, of record) in view of Applicant's admission regarding the prior art in the specification (see page 2) have been fully considered but are unpersuasive for reasons of record stated in the Final Office Action dated November 20, 2002.

Again, Applicants arguments regarding the Examiner's position that "applicant's admission regarding the prior art also teaches that a traumatic brain injury to CNS is tightly associated with GABA" are not found persuasive. As discussed in the Final Office Action, Applicant's admission regarding the prior art in the specification at page 2 lines 28-31 clearly teaches that "[f]ollowing a traumatic injury to the central nervous system, a cascade of physiological events leads to neuronal loss including, for example, an inflammatory immune response and excitotoxicity resulting from the initial impact disrupting .... $GABA_A$.. receptor system". Thus, Applicant's admission regarding the prior art in the specification clearly teaches that a traumatic brain injury to the central nervous system is tightly associated with GABA, and supports the Examiner's position.

Moreover, Applicants are requested to note that the claiming of a new use, new function or unknown property which is inherently present in the prior art method will not

make the claim nonobvious as set forth in the 103 rejection in the previous Office Action. Applicant's recitation of a new mechanism of action for the prior art method will not, by itself, distinguish the instant claims over the prior art teaching the same or nearly the same method steps. Mere recognition of latent properties in the prior art does not render novel or nonobvious an otherwise known invention. See *In re Wiseman*, 201 USPQ 658 (CCPA 1979).

Further, Applicants' assertion that a *prima facie* case of obviousness requires the prior art to suggest the claimed invention without references to the Applicants specification, is not found persuasive. As discussed in the Final Office Action, Applicants are also requested to note that what the Examiner cited in the rejection is the prior art as Applicant's admission in the specification – "Background of the Invention" in which Applicants admit those teachings are known before the invention herein.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning as a guide and selected references at random that mention various aspects of the claimed invention" and using hindsight reconstruction of the claimed invention, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. In re McLaughlin , 170 USPQ 209 (CCPA 1971). See MPEP 2145. As discussed in the previous Office Action, progesterone is known to be useful in

a method for treating a tramatic central system injury and a method of decreasing neurodegeneration in a subject following a traumatic injury to the central nervous system (CNS) according to the cited prior art. Allopregnanolone, is a well known to be a particular progesterone metabolite, having the same therapeutic usefulness as progesterone in CNS, e.g., neuroprotective properties modulating GABA receptor and increasing the effects of GABA, which is further supported by the disclosure in Gee et al. Therefore, one of ordinary skill in the art would have expected that the particular progesterone metabolite, allopregnanolone, would be useful in the claimed methods herein for treating a tramatic central system injury and decreasing neurodegeneration in a subject following a traumatic injury to CNS, as progesterone, with a reasonable success, absent evidence to the contrary.

Therefore, motivation to combine the teachings of the prior art to make the present invention is seen and no impermissible hindsight is seen. The claimed invention is clearly obvious in view of the prior art.

As discussed in the Final Office Action, Applicant's results shown in the Examples 1-7 of the specification at pages 20-40 herein have been fully considered with respect to the nonobviousness and/or unexpected results of the claimed invention over the prior art but are not deemed persuasive.

For the above stated reasons, said claims are properly rejected under 35 U.S.C. 103(a). Therefore, said rejection is adhered to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Jiang, whose telephone number is (703) 305-1008. The examiner can normally be reached on Monday-Friday from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, Ph.D., can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 305-1235.

S. Anna Jiang, Ph.D.
Patent Examiner, AU 1617
April 7, 2003